



PATENT  
Attorney Docket No. PTI-002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Kornblith                      CONFIRMATION NO.: 1251  
SERIAL NO.: 09/039,957                      GROUP NO.: 1651  
FILING DATE: March 16, 1998              EXAMINER: Gitomer, R.  
TITLE: METHOD FOR CULTURING AND ASSAYING CELLS

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Applicants note that references C23-C26 and C27 (previously submitted as reference AQ in the May 6, 2002, supplemental information disclosure statement) are being resubmitted as they were originally timely submitted, but not considered. Copies of the patents and publications are enclosed.

In addition, Applicants wish to inform the Examiner about the following patents and patent applications, and the contents of their file wrappers, including all Office actions issued therein:

- 1) U.S.S.N. 08/679,056, entitled "Method for Preparing Cell Cultures from Biological Specimens for Chemotherapeutic and Other Assays," filed on July 12, 1996, and issued on March 17, 1998, as U.S. Patent No. 5,728,541 (Reference D, cited in the April 15, 1999, PTO-892 form).
- 2) U.S.S.N. 09/095,993, entitled "Staining Agents and Protocols for Characterizing Malignant Cells in Culture," filed on June 11, 1998, and published on November 14, 2002, as U.S. Application Publication No. 2002/0168679 (Reference A24).
- 3) U.S.S.N. 09/189,310, entitled "Method of Using Multicellular Particulates to Analyze Malignant or Hyperproliferative Tissue," filed on November 10, 1998, and issued on July 9, 2002, as U.S. Patent No. 6,416,967 (Reference A, cited in the July 17, 2002, PTO-892 form).

- 4) U.S.S.N. 10/205,887, entitled "Method for Preparing Cell Cultures from Biological Specimens for Chemotherapeutic and Other Assays," filed on July 26, 2002, and published on December 19, 2002, as U.S. Application Publication No. 2002/0192638 (Reference A25).
- 5) U.S.S.N. 10/208,480, entitled "Method for Preparing Cell Cultures from Biological Specimens for Chemotherapeutic and Other Assays," filed on July 30, 2002, and published on February 5, 2004, as U.S. Application Publication No. 2004/0023375 (Reference A26).
- 6) U.S.S.N. 10/336,659, entitled "Methods for Assessing Efficacy of Chemotherapeutic Agents," filed on January 2, 2003, and published on April 15, 2004, as U.S. Application Publication No. 2004/0072722 (Reference A27).
- 7) U.S.S.N. 10/399,563, entitled "Method for Tandem Genomic/Proteomic Analysis of Proliferating Cells," filed on October 18, 2001, and published on May 6, 2004, as U.S. Application Publication No. 2004/0086888 (Reference A28).

### REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**

☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

#### STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [**check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required**]:

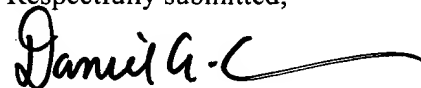
- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Date: May 26, 2004  
Reg. No. 45,508

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Respectfully submitted,



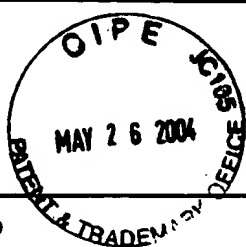
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SHEET 1 OF 2

FORM PTO - 1449				ATTORNEY DOCKET NO.: PTI-002					
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT				APPLICANT(S): Kornblith					
				SERIAL NO.: 09/039,957					
				FILING DATE: March 16, 1998 GROUP: 1651					
U.S. PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	A17	4,559,299	12/17/85	Rotman			02/04/83		
	A18	4,668,618	05/26/87	Thornthwaite			01/30/84		
	A19	4,816,395	03/28/89	Hancock <i>et al.</i>			12/19/85		
	A20	5,403,574	04/04/95	Piwnica-Worms			06/26/92		
	A21	5,705,270	01/06/98	Soon-Shiong <i>et al.</i>			06/07/95		
	A22	6,111,092	08/29/00	Williamson			06/03/98		
	A23	6,664,062 B1	12/16/03	Stanton			09/24/01		
	A24	2002/0168679 A1	11/14/02	Naus <i>et al.</i>			06/11/98		
	A25	2002/0192638 A1	12/19/02	Kornblith			07/26/02		
	A26	2004/0023375 A1	02/05/04	Kornblith <i>et al.</i>			07/30/02		
	A27	2004/0072722 A1	04/15/04	Kornblith <i>et al.</i>			01/02/03		
	A28	2004/0086888 A1	05/06/04	Kornblith <i>et al.</i>			10/18/01		
FOREIGN PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B1	WO96/10742	04/11/96	PCT			09/29/95	N	Y
	B2	WO98/02038	01/22/98	PCT			07/10/97	N	Y
	B3	WO02/33117A2	04/25/02	PCT			10/18/01	N	Y
	B4	WO2004/035833A1	04/29/04	PCT			10/10/03	N	Y
	B5	WO2004/015065A2	02/19/04	PCT			07/30/03	N	Y
EXAMINER					DATE CONSIDERED				



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		SERIAL NO.: 09/039,957	
		FILING DATE: March 16, 1998 GROUP: 1651	
OTHER ART, JOURNAL ARTICLES, ETC.			
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C23	Bosanquet, A.G., "Short-term <i>in vitro</i> drug sensitivity tests for cancer chemotherapy. A summary of correlations of test result with both patient response and survival," <i>Forum</i> 4(2):179-195 (1994).	
	C24	Fruehauf, J.P., "In vitro assay-assisted treatment selection for women with breast or ovarian cancer," <i>Endocrine-Related Cancer</i> 9:171-182 (2002).	
	C25	McGuire <i>et al.</i> , "In vitro assays to predict drug sensitivity and drug resistance: <i>A panel discussion</i> ," <i>Breast Cancer Research and Treatment</i> 12:7-21 (1988).	
	C26	Robert, J., "Chemosensitivity testing: Prediction of response to anticancer drugs using in vitro assays," <i>Electronic Journal of Oncology</i> 2:198-205 (1999).	
	C27	Kornblith, P., "Role of Tissue Culture in Prediction of Malignancy," <i>Clinical Neurosurgery</i> , Vol. 25, pp. 346-376 (1978).	
	C28	Freshney, R.I., <i>Culture of Animal Cells: A Manual of Basic Technique</i> , 2nd edition, pp. 107, 124-126, 179, 233-234, 290 (1987).	
	C29	Guo <i>et al.</i> , "Direct fluorescence analysis of genetic polymorphisms by hybridization with oligonucleotide arrays on glass supports," <i>Nucleic Acids Research</i> 22(24):5456-5465 (1994).	
	C30	Pfost <i>et al.</i> , "A SNPshot: pharmacogenetics and the future of drug therapy," <i>TIBTECH</i> 18:334-338 (August, 2000).	
	C31	Raju, G.C., "The histological and immunohistochemical evidence of squamous metaplasia from the myoepithelial cells in the breast," <i>Histopathology</i> 17(3):272-275 (1990).	
	C32	Stephens, J.C., "Single-nucleotide Polymorphisms, Haplotypes, and Their Relevance to Pharmacogenetics," <i>Molecular Diagnosis</i> 4(4):309-317 (1999).	
	C33	Tannock <i>et al.</i> , <i>The Basic Science of Oncology</i> , 2nd edition, pp. 247-248, 261-265, 303-306(1992).	
	C34	Becton-Dickinson Catalog, Anti-Cytokeratin (CAM 5.2) Reagent, pp. 1-11 (1997).	
	C35	Boehringer Mannheim Catalog, Anti-Cytokeratin AE1/AE3, (1996).	
	C36	DAKO Catalog, Specification Sheet for Monoclonal Mouse Anti-Human Epithelial Membrane Antigen, pp. 1-2 (1996).	
EXAMINER		DATE CONSIDERED	